

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

This document relates to:

*The County of Cuyahoga v. Purdue
Pharma L.P., et al.*, Case No. 17-OP-45004

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P. et al.,
Case No. 18-OP-45090*

**EXHIBIT A
SUMMARY SHEET FOR
DEFENDANTS' MOTION TO EXCLUDE
LACEY KELLER'S OPINIONS AND PROPOSED TESTIMONY**

Reply Name: Defendants' Reply In Support of Defendants' Motion to Exclude Lacey Keller's Opinions and Proposed Testimony

Moving Parties: Defendants

Concise Description of Issues:

Issue 1: Does Plaintiffs' Opposition demonstrate that the methodology underlying Keller's calculations of "suspicious orders" is reliable?

Answer: **No.** Plaintiffs concede that Keller does not claim to apply the legal definition of "suspicious order" under the Controlled Substances Act ("CSA"). In addition, she takes many different companies' customized suspicious order monitoring ("SOM") metrics and applies them indiscriminately to **all** opioid prescriptions—but those business-specific metrics were never intended to be applied universally. In addition, she incorrectly assumes that any order that triggers those metrics is "suspicious," when in reality orders flagged by a given company's metrics need not be reported to the DEA if subsequent due diligence shows them to be legitimate. Keller's calculations thus cannot help the jury answer the only question relevant to the diversion inquiry: whether Defendants failed to identify and report suspicious orders under the CSA. They should be excluded as a result.

Issue 2: Does Plaintiffs' Opposition rehabilitate Keller's small labeler opinion?

Answer: **No.** Keller's small labeler opinion rests on the false and unsupported assumption that a physician would have been stopped from ever prescribing another opioid medication immediately after a small labeler such as Janssen reported his or her suspicious prescribing to the DEA. Evidence demonstrates that the DEA investigates only a tiny fraction of all reported suspicious orders, and even doctors who were reported, investigated, and indicted for over-prescribing continued prescribing pharmaceuticals for months after the investigations into their practices began. Accordingly, this portion of Keller's testimony is additionally inadmissible and should be excluded.

Issue 3: Does Plaintiffs' Opposition demonstrate that Keller's use of 2018 IQVIA data is reliable or relevant?

Answer: **No.** IQVIA data changes constantly and there is no evidence that the IQVIA data Defendants had access to in the past actually resembled the 2018 data Keller analyzed. Plaintiffs try to shift the burden under *Daubert* by arguing that there is no evidence those differences were material. But Plaintiffs bear the burden to establish the reliability and relevance of Keller's analysis, and their failure to show that the data she analyzed resembles what was available to Defendants renders her opinions inadmissible.

Issue 4: Does Plaintiffs' Opposition rehabilitate Keller's opinion purporting to trace Mallinckrodt orders from distributors to customers reliable?

Answer: **No.** Plaintiffs concede that Keller cannot "trace" Mallinckrodt's orders to shipments distributors made to the Counties as she purports to do in her report. Plaintiffs offer no answer to defense expert Edward Buthusiem's explanation of why such "tracing" is functionally impossible and offer no basis for their contention that Keller's testimony on this point could nevertheless provide some "estimate" that could assist the finder of fact. Keller's opinions and testimony on this point must be excluded as well.